

REMARKS

In the present Amendment, the claims have been amended to delete “halogen” and “C₁₋₅ alkoxy” from the definitions of Z₂ and Z₄ and “C₁₋₅ alkyl” from the definitions of R₂ and Z₃. In addition, the claims have been amended to delete the recitation “hydrate and/or solvate.” Claim 13 has been amended to correct “halaogen” to --halogen--. Claims 21-44 have been cancelled without prejudice or disclaimer. No new matter has been added, and entry of the Amendment is respectfully requested.

Upon entry of the Amendment, claims 1-20 and 45 will be pending.

Response to § 112 Rejection and § 101 Rejection of Claims 24-28

At page 2 of the Action, claims 24-28 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, allegedly because claims 24-28 merely recite a use without any active, positive steps delimiting how this use is actually practiced.

At page 16 of the Action, claims 24-28 are rejected under 35 U.S.C. § 101 because, per the Examiner, the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101.

As noted, claims 24-28 have been cancelled, rendering the above rejections moot.

Response to § 112 Rejection of Claims 1-45

At page 2 of the Action, claims 1-45 are rejected under 35 U.S.C. § 112, first paragraph, because, per the Examiner, the specification, while being enabling for making pharmaceutically acceptable salts, does not reasonably provide enablement for making hydrates or solvates.

As noted, the recitation of “hydrate and/or solvate” has been deleted. Accordingly, withdrawal of the § 112 rejection is respectfully requested.

Response to § 112 Rejection of Claims 21-44

At page 7 of the Action, claims 21-44 are rejected under 35 U.S.C. § 112, first paragraph, because, per the Examiner, the specification, while being enabling for obesity and diabetes, does not reasonably provide enablement for prophylaxis of diabetes and obesity as well as prophylaxis or treatment of the other disorders recited in the claims.

As noted, claims 21-44 have been cancelled, rendering this rejection moot.

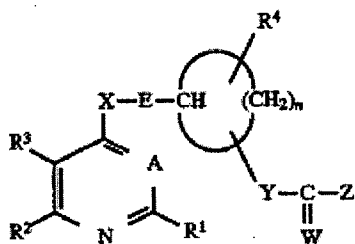
Response to §§ 102/103(a) Rejections based on Schaper et al

At page 17 of the Action, claims 1-6, 9-15, 18 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Schaper et al (US 5,691,321).

At page 19 of the Action, claims 1-6, 9-15, 18 and 19 are rejected under 35 U.S.C. § 103(a) as being obvious over Schaper et al.

The above two rejections should be withdrawn because Schaper et al does not disclose or render obvious the present invention.

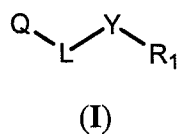
Schaper et al teaches heterocyclic compounds of formula I shown below:



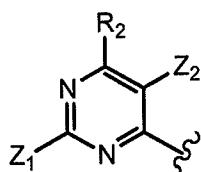
Formula I of Schaper et al

wherein A is CH or N; X is NH, O or S; E is a bond or a straight chain or branched (C₁-C₄)-alkanediyl group; Y is oxygen or a direct bond; W is oxygen or sulfur; and Z is a radical DR⁵ or NR⁵R⁶, D is oxygen, sulfur or a direct bond, R⁵ and R⁶ are hydrogen, alkyl, alkenyl, alkynyl, aryl or heterocyclyl (cols. 1 and 2).

Present claim 1 relates to a compound of Formula (I):

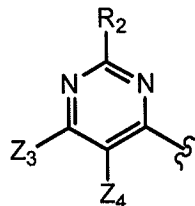


wherein Q is



(IIa)

or



(IIb)

Substituent R³ of the compounds in Table 1 of Schaper et al corresponds to Z₂ or Z₄ of the presently claimed Formula (I) wherein Q is (IIa) or (IIb).

The compounds listed in Table 1 of Schaper et al are those in which R³ is halogen, -CN or -OCH₃. The compounds in Examples A through F and I are also limited to those in which R³ is halogen, -CN or -OCH₃.

However, "halogen" and "C₁₋₅ alkoxy" have been deleted from the definition of Z₂ and Z₄. Therefore, the claims as amended are not anticipated by or obvious over Schaper et al.

Further, the compounds of Schaper et al are pesticides and fungicides. In contrast, the instantly claimed compounds are suitably incorporated into pharmaceutical compositions.

Therefore, one of ordinary skill in the art would not have arrived at the present invention from the teaching of Schaper et al.

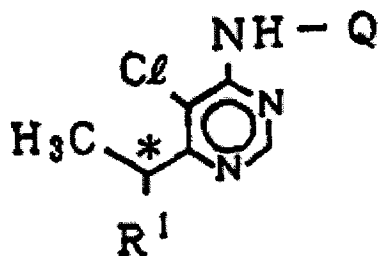
In view of the above, reconsideration and withdrawal of the §§102(b)/103(a) rejections based on Schaper et al are respectfully requested.

Response to § 102 Rejection based on Obata et al

At page 17 of the Action, claims 1-6, 9-15, 18 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Obata et al (WO 96/06086).

This rejection should be withdrawn because Obata et al does not disclose or render obvious the present invention.

Obata et al teaches compounds of formula I shown below:



Formula I of Obata et al

wherein Q is represented by (Qa):



Obata et al teaches specific compounds in Table 2 at pages 51-65.

The compounds listed in Table 2 of Obata et al contain chlorine on the pyrimidine nucleus. The position at which the chlorine is carried corresponds to Z₂ or Z₄ of the presently claimed Formula (I) wherein Q is (IIa) or (IIb).

However, "halogen" has been deleted from the definition of Z₂ and Z₄. Therefore, the claims as amended are not anticipated by Obata et al.

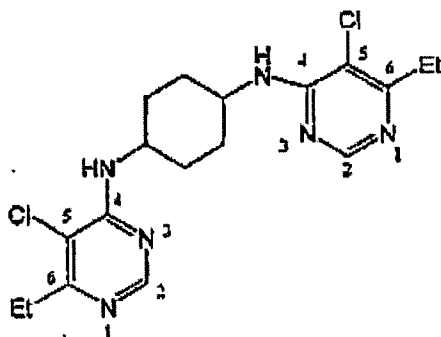
In view of the above, reconsideration and withdrawal of the §102(b) rejection based on Obata et al are respectfully requested.

Response to § 102 Rejection based on Lee et al

At page 17 of the Action, claims 1-6, 9-15, 18 and 19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lee et al (WO 99/31072).

This rejection should be withdrawn because Lee et al does not disclose or render obvious the present invention.

In Lee et al, the actually prepared compounds are enumerated in Index Tables A, B and C on pages 92-96. In Index Table A, there are several compounds containing a pyrimidine nucleus. See column G of the Table. For example, the compound of Ex. No. 1 in Index Table A on page 92 is as follows:



When compared with the pyrimidine nucleus of the presently claimed Formula (I) wherein Q is (IIa) or (IIb), the 5-position of the above formula corresponds to Z₂ or Z₄ of the presently claimed Formula (I) and the 6-position (-Et) of the above formula corresponds to R₂ or Z₃ of the presently claimed Formula (I). The 6-position of the pyrimidine nucleus-containing compounds listed in Index Tables A, B and C is substituted with MeOCH₂- or Et-.

However, the definitions of R₂ and Z₃ of the presently claimed Formula (I) do not include an alkyl substituted by alkoxy, i.e., they cannot be MeOCH₂-. Further, "C₁₋₅ alkyl" has been deleted from the definitions of R₂ and Z₃. Therefore, the instantly claimed compounds are novel over the compounds enumerated in Index Tables A, B and C of Lee et al.

Additionally, the compounds in Tables 1-26 on pages 26-85 of Lee et al were not actually prepared and are therefore speculative.

However, Applicants would like to make a close look at the differences between the instantly claimed compounds and the speculative compounds of Lee et al.

In the compounds containing any of the pyrimidine scaffolds, Q-1, Q-2, Q-3 and Q-4 on page 26 of Lee et al, the positions corresponding to R₂ and Z₃ of the presently claimed Formula (I) wherein Q is (IIa) and (IIb), respectively, are always substituted with Et-, MeOCH₂- or cyclopropyl-.

However, the definitions of R₂ and Z₃ of the presently claimed Formula (I) do not include an alkyl substituted by alkoxy, i.e., they cannot be MeOCH₂-, and do not include cycloalkyl either. Further, "C₁₋₅ alkyl" has been deleted from the definitions of R₂ and Z₃. In the compounds enumerated in Tables 5-8 containing a pyrimidine scaffold, the position R² corresponding to R₂ and Z₃ of the presently claimed Formula (I) wherein Q is (IIa) and (IIb), respectively, is always Me-, cyclopropyl-, MeOCH₂- or Et-.

In conclusion, the instantly claimed compounds are novel over the compounds in Tables 1-26 on pages 26-85 of Lee et al for the same reasons as discussed with regard to the compounds enumerated in Index Tables A, B and C of Lee et al.

In view of the above, reconsideration and withdrawal of the §102(b) rejection based on Lee et al are respectfully requested.

Response to §§ 102/103(a) Rejections based on Sekiguchi et al

At page 18 of the Action, claims 1-45 are rejected under 35 U.S.C. § “102(e)” as being anticipated by Sekiguchi et al (EP 1,464,335).

At page 19 of the Action, claims 1-45 are rejected under 35 U.S.C. § 103(a) as being obvious over Sekiguchi et al.

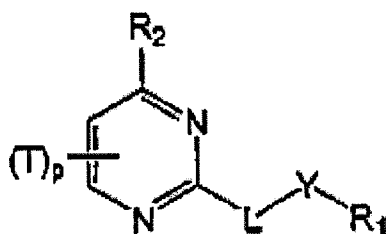
The above two rejections should be withdrawn because Sekiguchi et al does not disclose or render obvious the present invention.

Initially, the Examiner states that based upon the earlier effective U.S. filing date of Sekiguchi et al, it constitutes prior art under 35 U.S.C. § 102(e).

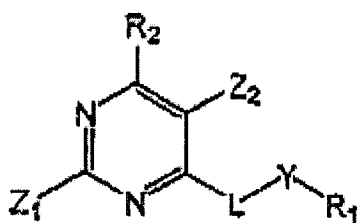
However, Sekiguchi et al is not a U.S. patent application publication, a U.S. patent or a WIPO publication of an international application. Accordingly, it cannot be applied under § 102(e).

In fact, Sekiguchi et al was published on October 6, 2004, which is less than one year prior to the March 29, 2005 PCT filing date of the present application but later in time than Applicants' priority date of March 30, 2004 (U.S. provisional Application No. 60/557,406). Accordingly, Sekiguchi et al is disqualified as a reference.

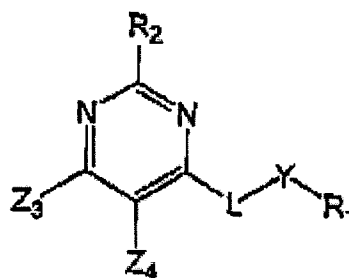
In addition, the compounds of Sekiguchi et al are as follows when R1 is formula IV:



In contrast, the instantly claimed compounds are:



or



As clearly seen from the comparison of the above formulas, the instantly claimed compounds differ from the compounds of Sekiguchi et al in the arrangement of nitrogen atoms within the pyrimidine ring. The structural difference therebetween is significant. Therefore, one of ordinary skill in the art would not have been motivated to replace the pyrimidine nucleus taught by Sekiguchi et al with the nucleus defined by the present claims.

In view of the above, the present claims are not anticipated by or obvious over Sekiguchi et al. Reconsideration and withdrawal of the §§"102(e)"/103(a) rejections based on Sekiguchi et al are respectfully requested.

Allowance is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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